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**REMARKS**

Claims 1, 2, 6, 10 and new Claims 11 and 12 are pending in the application.

Claim 1 has been amended to reflect that the claimed salts are beneficially water soluble and exhibit improved water solubility in comparison to the amino acid alone. Support for this amendment can be found in the Application-as-filed, for example on Page 2, lines 30 through 31.

Claims 11 and 12 have been added to complete the record for examination and highlight advantageous embodiments of the invention.

Claim 11 is directed to advantageous salts of the invention formed from protonated sweetener. Support for Claim 11 can be found in the Application-as-filed, for example on Page 2, lines 16 through 24.

Claim 12 is directed to advantageous salts of the invention which are formed from arginine. Support for Claim 12 can be found in the Application-as-filed, for example in Claim 2.

Applicants respectfully submit that this response does not raise new issues, but merely places the above-referenced application either in condition for allowance, or alternatively, in better form for appeal. Reexamination and reconsideration of this application, withdrawal of all rejections, and formal notification of the allowability of the pending claims are earnestly solicited in light of the remarks which follow.

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*The Claimed Invention is Patentable in  
Light of the Art of Record*

Claims 1, 2, 6 and 10 stand rejected over European Patent Application 0122400 to Nakajima ("Nakajima"), United States Patent No. 5,298,648 to Ebisawa et al. ("Ebisawa") and United Kingdom Patent Application 1297741 to Ninomiya et al. ("Ninomiya") in view of WIPO Publication No. 99/04822 to Ledniczky et al ("Ledniczky") and WIPO Publication No. 00/12067 to Rayburn ("Rayburn").

It may be useful to briefly consider the invention before addressing the merits of the rejection.

It is considered beneficial to incorporate amino acids, particularly arginine and lysine, into foodstuffs. Unfortunately, many amino acids have a bitter taste, especially arginine. Sweeteners, such as artificial sweeteners, may be mixed with the amino acids to counteract the bitterness of the amino acids. However, Applicants have noted that simple mixtures formed from artificial sweeteners and amino acids can separate back out into their component parts, leading to unpleasant inhomogeneities in the taste of the resulting foodstuffs. Further, an excessive amount of the artificial sweeteners themselves may introduce an unpleasant taste or aftertaste.

Surprisingly, Applicants have determined that two quite dissimilar components, i.e. amino acids and artificial sweeteners, can be ionically bonded to produce salts that can be recovered from a solution, such as an aqueous solution. (The Examiner's attention is kindly directed to the Application-as-filed on Page 2, lines 30 – 33).

Applicants respectfully reiterate that the claimed salt formation was quite unexpected, as it can be problematic to form and/or recover salts from solution. Although numerous compounds are known to form ionic species upon dissolution in a solvent, particular conditions must be

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present for ionic reactants to form a recoverable salt product, as described in the declaration of Dr. Burgard, forwarded with Applicant's Amendment of November 19, 2004.

Applicants have further determined artificial sweeteners having particularly enhanced acidic-reacting tendencies in advantageous embodiments of the invention. Artificial sweeteners are typically commercially available as alkali metal salts, such as potassium or sodium salts. The artificial sweetener acesulfame is commercially sold in the form of its potassium salt, acesulfame K, for example. Similarly, saccharine is commercially available as sodium saccharine. (The Examiner's attention is kindly directed to Ninomiya at Page 1, lines 25 – 27, for example). Although these salts dissociate in water, they do not necessarily form precipitated salts with other components within a liquid composition, as evidenced by several of the cited references and the newly submitted declaration by Dr. Burgard, attached as Exhibit I ("the attached declaration"). Applicants have found that the acidic-reacting properties of such commercially available artificial sweeteners can be advantageously be enhanced via protonation to react readily with amino acids to form salts, as reflected in Claim 11.

Applicants have further discovered that the salts of the invention, which are water soluble, exhibit improved water solubility in comparison to the amino acid alone (and thus blends thereof), as reflected in Claim 1 as-amended and described in greater detail within the attached declaration by Dr. Burgard. As noted within the declaration, recent testing indicates that the claimed salts advantageously provide up to a 16 X increase in water solubility in comparison to the corresponding blend. Such improved water solubility is highly beneficial in incorporating the resulting salts into foodstuffs.

Applicants have further determined that salts formed in accordance with the invention additionally provide a more balanced taste profile in comparison to the corresponding blend. A taste test evidencing the improved tastes profile of salts in accordance with the invention in comparison to the corresponding blend is provided in the attached declaration, as well. Such an improved taste profile, even in the absence of component separation, is altogether surprising and highly advantageous.

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Accordingly, the claims are directed to salts derived from a basic-reacting amino acid with at least one acidic-reacting sweetener, in which the amino acid and sweetener are present in a discrete, stoichiometric molecular ratio of either 1:1 or 1:2. The resulting salt is water soluble and has an improved water solubility in comparison to the amino acid alone.

Applicants have further determined that dibasic amino acids can be reacted with two different artificial sweeteners to provide salts that have an overall improved sweetness profile, as reflected in Claim 6. Applicants have found that by reacting dibasic amino acids with two different artificial sweeteners, amino acid salts are provided that have a highly advantageous time course of sweetness and sweetness intensity. In one especially advantageous embodiment, amino acid salts incorporating both acesulfame and saccharine are provided, as recited in Claim 10.

Altogether unexpectedly, Applicants have found that even the extreme bitterness of arginine can be addressed by the salts of the invention, as reflected in Claim 12.

Applicants respectfully reiterate that the cited references do not teach or suggest the claimed invention.

Nakajima is merely directed to mixtures, which Nakajima repeatedly refers to as "compositions," incorporating acesulfame K. (Page 2, lines 13 – 15; Page 3, lines 7, 27 and 34; Page 4, lines 8 and 27 et al.). Nakajima initially notes that although acesulfame K has been found to have a sweet taste, it has a bitter tone to its sweetness. (Page 1, line 24 – Page 2, line 2). Nakajima then attempts to improve the overall taste of the sweetener by merely *mixing* acesulfame K with any of a laundry list of additives. (Page 2, lines 6 – 10).

Nakajima teaches that his compositions may be formed by mixing acesulfame K and additive as dry powders, clearly evidencing the lack of salt formation. (Page 4, lines 1 – 7). Nakajima then goes on to disclose that the acesulfame K and additive may even be added to

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foods separately. (Page 5, lines 9 through 12). Applicants respectfully reiterate that such mixtures of acesulfame K and additive would not form salts, as discussed within Dr. Burgard's declaration of November 3, 2004 (Paragraph 17); as evidenced within Dr. Burgard's attached declaration (failure of sodium saccharine and arginine to form salt); and further evidenced by Nakajima on Page 7, lines 1 through Page 11, line 7 (failing to note any salt precipitation within numerous exemplary foodstuffs incorporating various acesulfame K mixtures).

Nakajima provides additional evidence of his lack of salt formation by his recommendation of a broad range of additive to acesulfame K amounts. Nakajima more particularly discloses the use of up to 40 times more additive than acesulfame K. (Page 3, lines 10 – 14). Applicants respectfully submit that it would be stoichiometrically impossible to form salts incorporating 40 times more additive than acesulfame K.

Furthermore, Nakajima's laundry list of additives merely includes "certain" amino acids. (Page 2, lines 6 – 8). Nakajima clearly indicates that not all amino acids are suitable for use in his mixtures. Nakajima goes on to expressly indicate that arginine is not effective in improving the taste of acesulfame K, for example. (Page 6, Table 1, line 14). Such a result is not surprising, given the extremely bitter taste of arginine.

Applicants thus respectfully reiterate that Nakajima, whether considered alone or in combination with the art of record, does not teach or suggest the recited salts. Nakajima is instead solely directed to mixtures.

As Nakajima does not teach or suggest salts, he most certainly does not teach or suggest the recited salts exhibiting improved water solubility in comparison to the amino acid alone.

Nakajima, disclosing up to 40 times more additive than acesulfame K, further does not teach or suggest the recited salts in which the amino acid and protonated sweetener are present in a discrete stoichiometric molecular ratio of either 1:1 or 1:2.

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Nakajima, directed to a single sweetener, does not teach or suggest amino acid – based salts that include two different sweeteners within the same molecule, as recited in Claim 6. Thus Nakajima most certainly does not teach or suggest salts including both acesulfame and saccharine, as recited in Claim 10.

Nor does Nakajima, directed solely to acesulfame K, teach or suggest salts incorporating protonated sweetener, as recited in Claim 11.

And Nakajima most certainly does not teach or suggest salts comprising arginine, as recited in Claim 12. Nakajima instead strongly teaches away from such embodiments by expressly indicating that mixtures incorporating acesulfame K and arginine are “not effective.”

Accordingly, Applicants respectfully submit that Claims 1, 2, 6, and 10 through 12 are patentable in light of Nakajima, considered either alone or in combination with the art.

Ninomiya is similarly directed to mixtures intended to address the unpleasant aftertaste normally associated with a different artificial sweetener salt, namely sodium saccharin. (Page 1, lines 30 – 35). Ninomiya purportedly reduces the unpleasant after-taste associated with sodium saccharin by admixing tryptophan with sodium saccharin. (Page 1, lines 50 – 55). Ninomiya expressly refers to the resulting combination as either a “composition” or a “mixture.” (Page 1, lines 42 – 52 and Page 3, lines 5 - 20).

Applicants respectfully reiterate that Ninomiya’s mixtures of sodium saccharine and typtophan would not form the recited salts, as discussed within Dr. Burgard’s declaration of November 3, 2004 (Paragraph 14); as evidenced within Dr. Burgard’s attached declaration (failure of sodium saccharine and arginine to form salt); and further evidenced by Ninomiya’s lack of any indication that exemplary beverages incorporating his sodium saccharin mixtures form a precipitate. (Page 2, lines 18 through 28).

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Ninomiya notes the incorporation of up to 200 times more tryptophan than sodium saccharin. (Page 1, lines 42 – 50). Applicants respectfully submit that it would be stoichiometrically impossible to form a salt incorporating 200 times more tryptophan than sodium saccharine.

Applicants thus respectfully reiterate that Ninomiya, whether considered alone or in combination with the art of record, does not teach or suggest the recited salts. Ninomiya is instead solely directed to mixtures.

Ninomiya, disclosing the incorporation of up to 200 times more tryptophan than sodium saccharin, further does not teach or suggest the recited salts in which the amino acid and sweetener are present in a discrete, stoichiometric molecular ratio of either 1:1 or 1:2.

Ninomiya, directed to mixtures that include a single sweetener, does not teach or suggest amino acid – based salts that include two different sweeteners within the same molecule, as recited in Claim 6. And Ninomiya most certainly does not teach or suggest such salts including both acesulfame and saccharine, as recited in Claim 10.

Nor does Ninomiya teach or suggest such salts formed from protonated sweeteners and amino acids, as recited in Claim 11. Nakajima is instead solely directed to mixtures incorporating sodium saccharin.

Ninomiya further does not teach or suggest salts comprising the particularly bitter arginine, as recited in Claim 12. Ninomiya is instead solely directed to tryptophan.

Accordingly, Applicants respectfully submit that Claims 1, 2, 6, 10 through 12 are patentable in light of Ninomiya, considered either alone or in combination with the art.

Ebisawa is even further removed from the claimed invention. Ebisawa is merely directed to the use of crystal growth inhibitors to form thicker and firmer aspartame crystals. (Col. 2,

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lines 12 – 18). Ebisawa provides a laundry list of suitable crystal growth inhibitors, including organic acids, such as citric acid. (Col. 2, lines 32 – 45). The crystal growth inhibitor is present in a maximum amount of 5 % of the weight of the aspartame to be crystallized, i.e. Ebisawa teaches the use of a minimum of 19 times more aspartame than crystal growth inhibitor. (Col. 2, line 66 – Col. 3, line 1; see also Example 1 at Col. 3, lines 61 – 65 (10 mg crystal growth inhibitor to 2 g aspartame) and Example 2 at Col. 4, lines 10 – 12 (15 mg crystal growth inhibitor to 1 g aspartame)).

The crystals ultimately produced by Ebisawa are solely aspartame, and do not contain the crystal growth inhibitor. (Col. 4, lines 27 – 35). In fact, Ebisawa actually refers to his method as a means to purify aspartame. (Col. 3, lines 39 – 41).

Ebisawa, whether considered alone or in combination with the art of record, thus does not teach or suggest the recited salts. Ebisawa teaches away from the recited salts by instead disclosing that crystal growth inhibitor and aspartame fail to even form a stable mixture, i.e. the aspartame is ultimately separated from the growth inhibitor by design.

Ebisawa further does not teach or suggest the recited salts including amino acid and artificial sweetener in a discrete, stoichiometric molecular ratio of either 1:1 or 1:2. Ebisawa instead teaches the use of a significantly greater quantity of aspartame than crystal growth inhibitor.

Ebisawa, directed to pure aspartame crystals, does not teach or suggest amino acid – based salts that include two different sweeteners within the same molecule, as recited in Claim 6. Thus Ebisawa most certainly does not teach or suggest salts including both acesulfame and saccharine, as recited in Claim 10.

And Ebisawa most certainly does not teach or suggest salts derived from amino acid and a protonated artificial sweetener, as recited in Claim 11.



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Nor does Ebisawa teach or suggest salts comprising arginine, as recited in Claim 12.

Accordingly, Applicants respectfully submit that Claims 1, 2, 6, 10 through 12 are patentable in light of Ebisawa, considered either alone or in combination with the art.

The secondary references do not cure the deficiencies within the primary references.

Rayburn is directed to compounds formed from "certain" mono-cationic pharmaceuticals and sodium saccharinate. (Page 1, lines 7 – 8 and Page 2, lines 15 – 18). Rayburn's particular pharmaceuticals are non-alkaloid, i.e. non-nitrogenous compounds. (Page 2, lines 10 – 11). Rayburn emphasizes repeatedly the reduction in the water solubility of his compositions in comparison to the non-alkaloid alone. (Page 1, lines 29 – 31; Page 2, lines 6 – 8 and 11 - 15 and Page 5, lines 8 – 11). In fact, Rayburn touts that his compounds provide sustained release due to their "decreased aqueous solubility." (Page 2, lines 11 – 13). Rayburn goes on to evidence the poor water solubility of his compounds by noting their recovery from a methylene chloride solution. (Page 5, lines 18 – 25).

Applicants respectfully reiterate that Rayburn does not teach or suggest the recited amino acid-based salts, which by are by definition nitrogenous compounds. In fact, Rayburn strongly teaches away from such compounds by requiring a non-alkaloid.

And Rayburn most certainly does not teach or suggest the recited amino-acid based salts that exhibit improved water solubility in comparison to the amino acid alone. Rayburn instead strongly teaches away from such salts, by emphasizing the reduced solubility of his compounds.

Rayburn, directed to mono-cationic pharmaceuticals, does not teach or suggest amino acid – based salts that include two different sweeteners within the same molecule, as recited in Claim 6. Thus Rayburn most certainly does not teach or suggest salts including both acesulfame and saccharine, as recited in Claim 10.

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Rayburn, directed solely to sodium saccharine, further does not teach or suggest amino-acid based salts derived from a protonated artificial sweetener, as recited in Claim 11.

Nor does Rayburn teach or suggest salts comprising arginine, as recited in Claim 12. In fact, Rayburn teaches away from the use of nitrogen-based components, as noted above.

Accordingly, Applicants respectfully submit that Claims 1, 2, 6 and 10 through 12 are patentable in light of Rayburn, considered either alone or in combination with the art.

Ledniczky similarly does not teach or suggest the recited amino acid salts. Ledniczky is also directed to the use of sweeteners to improve the taste of mono-cationic pharmaceuticals. Ledniczky generically notes that his compounds can be prepared using methods "known per se." (Page 6, lines 16 – 18). Ledniczky expressly teaches the use of sweeteners that are "commercial products." (Page 6, line 21). Ledniczky then goes on to disclose the use of sodium cyclamate, a commercially available sweetener, to form a compound that is soluble in an alcohol/water solution. (Page 7, lines 25 – Page 8, line 20). Ledniczky further indicates that saccharimide may be used to form solvates that are alcohol soluble. (Page 7, lines 1 – 10).

Applicants respectfully reiterate that Ledniczky does not teach or suggest the recited amino acid-based salts.

And Ledniczky, disclosing alcohol soluble solvates, most certainly does not teach or suggest the recited amino-acid based salts that are water soluble and further exhibit improved water solubility in comparison to the amino acid alone.

Ledniczky, directed to mono-cationic pharmaceuticals, does not teach or suggest amino acid – based salts that include two different sweeteners within the same molecule, as recited in Claim 6. Thus Ledniczky most certainly does not teach or suggest salts including both acesulfame and saccharine, as recited in Claim 10.

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Ledniczky, teaching the use of commercially available sweeteners, further does not teach or suggest such amino-acid based salts derived from a protonated artificial sweetener, as recited in Claim 11.

Nor does Ledniczky teach or suggest salts comprising arginine, as recited in Claim 12.

Accordingly, Applicants respectfully submit that Claims 1, 2, 6, and 10 through 12 are patentable in light of Ledniczky, considered either alone or in combination with the art.

Applicants further respectfully submit that there would have been no motivation to have combined these references, which are in altogether different fields of endeavor. Nakajima and Ninomiya are directed to *mixtures* that purportedly improve the taste of commercially available artificial sweeteners. Ebisawa does not even teach mixtures, but is instead directed to the formation of improved aspartame crystals. Rayburn and Ledniczky are directed to improved pharmaceuticals. These are altogether different fields of endeavor.

Applicants respectfully reiterate that there further would have been no motivation to form the claimed amino acid salts, which have altogether different chemical structures and utilities from the compounds of Rayburn or Ledniczky. Applicants again note that the chemical arts are unpredictable, particularly regarding the expected efficacies of various compounds. Thus the efficacies of Rayburn or Ledniczky can not be imputed to the claimed amino acid-based salts, particularly in light of the structural dissimilarities between Rayburn or Ledniczky's drugs and the recited amino acids. Further, there is no similarity in utility between Rayburn or Ledniczky and the claimed amino acid-based salts. Rayburn and Ledniczky are each directed to various families of drugs. In contrast, the claimed amino acids are primarily used as food additives. Applicants thus respectfully submit that the claimed invention is patentable, based solely on the lack of similarity of chemical structure and utility for the claimed invention versus the art of record.

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Applicants additionally submit that there would have been no motivation to have combined these references, as there would have been no expectation of success based on Ebisawa. In particular, Ebisawa clearly teaches that the combination of aspartame and growth inhibitor not only fails to react but even fail to form a stable mixture, as pure aspartame is ultimately produced. Hence there would have been no expectation that the recited combination of amino acid and sweetener would have resulted in the claimed salts. Further, the claimed salts would render Ebisawa unfit for its intended purpose as a crystallization method for pure aspartame.

However, even if one had combined the references (which Applicants submit should not be done), the claimed invention would not have resulted. Nakajima and Ninomiya each clearly require *mixtures* based on commercially available artificial sweeteners. Ebisawa requires the formation of pure aspartame. Rayburn requires non-alkaloids, i.e. non-nitrogenous compounds, which are used to form compounds that are less water soluble. Ledniczky teaches the use of commercially available artificial sweeteners to form alcohol solvates.

Accordingly, none of the references, considered either alone or in combination, teach or suggest the recited salts derived from a basic-reacting amino acid and an acidic-reacting artificial sweetener, much less such salts in which the amino acid and sweetener are present in a discrete, stoichiometric molecular ratio of either 1:1 or 1:2.

And the combination most certainly does not teach or suggest the recited amino-acid based salts that are water soluble and further exhibit improved water solubility in comparison to the amino acid alone. As noted above, the secondary references instead teach away from such a recitation.

Nor does the combination teach or suggest amino acid – based salts that include two different sweeteners within the same molecule, as recited in Claim 6. The combination similarly fails to teach or suggest salts including a dibasic amino acid, acesulfame and saccharine, as recited in Claim 10.

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The combination, each teaching the use of commercially available sweetener, further does not teach or suggest amino-acid based salts derived from a protonated artificial sweetener, as recited in Claim 11.

The combination likewise fails to teach or suggest salts comprising the bitter-tasting arginine, as recited in Claim 12.

Applicants thus respectfully submit that the claimed invention is patentable in light of the art of record, considered either alone or in combination.

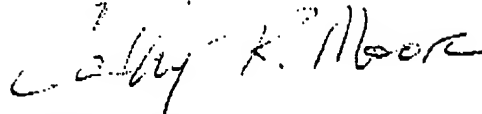
### **CONCLUSION**

It is respectfully submitted that Applicants have made a significant and important contribution to the art, which is neither disclosed nor suggested in the art. It is believed that all of pending Claims 1, 2, 6 and 10 through 12 are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions or fees are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions or fees are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 50-2193.

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Respectfully submitted,



Cathy R. Moore  
Reg. No. 45,764

ProPat, L.L.C.  
425-C South Sharon Amity Road  
Charlotte, North Carolina 28211-2841  
Telephone: (704) 365-4881  
Fax: (704) 365-4851

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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office at facsimile number \_\_\_\_\_ on August 1, 2005.

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